TFW 1616

Attorney Docket # 4948-2PCRCE3 PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of

Carlos PICORNELL DARDER

Serial No.: 09/491,624

Filed: January 26, 2000

For: Oral Pharmaceutical Preparation Comprising an Antiulcer Activity Compound, and Process for its Production

Examiner: Sharmila S. Gollamudi
Group Art: 1616

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Vincent M. Fazzari
Name of applicant, assignee or Registered Representative

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July 7, 2006
Date of Signature

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VOLUNTARY SUBMISSION

SIR:

This is a Voluntary Submission by Applicant in the above-identified application. Applicant also requests a corrected Interview Summary for the reasons set forth below.

On May 18, 2006, undersigned counsel conducted a telephone interview with Examiners Richter (SPE) and Gollamudi. During the interview, reference was made to WO 96/01624 ("WO '624") which had been cited against a foreign counterpart application. Applicant's undersigned attorney advised at the time that he believed U.S. Patent No. 5,753,265 was a U.S. counterpart, or based on, WO '624.

In the Interview Summary mailed from the PTO on June 2, 2006, the Examiner indicated that Applicant's counsel had represented that the U.S. patent (presumably U.S. '265) contained

stability data. However, no such representation was made. Applicant's attorney did indicate that Lovgren's U.S. Patent No. 4,786,505 contained data comparing omeprazole formulations with and without an intermediate layer and showing rapid degradation, or lack of stability, in those formulations which were made without a separating layer between the core region (containing the active ingredient) and the enteric coating. Applicant thus wishes to have the record corrected. Applicant's attorney did phone the Examiner to request a corrected Interview Summary but, as of the date of the filing of this paper, no corrected Interview Summary has been received.

Enclosed herewith is the Declaration of Dr. Carmen Molina-Millián who is an employee of the assignee of the above-identified application. Dr. Molina-Millián is the same individual who previously submitted a declaration in this matter ("the Molina Declaration").

In the present declaration, Dr. Molina-Millián reports on another comparative test. In this test, the declarant fairly reproduced the first step of Example 11 of WO '624 to obtain enteric coated pellets prior to those pellets being compressed to form tablets. The details of the procedure are set forth in the enclosed declaration. The declarant produced enteric coated pellets of lansoprazole and pantoprazole, both of which are substituted benzimidazoles. As noted in Paragraph 10 of the declaration, in each instance, a core material with a creamy white color was obtained prior to the application of the enteric coating.

Annex 1 attached to the declaration shows, in Figure 1, enteric coated lansoprazole pellets and, in Figure 2, enteric coated pantoprazole pellets each according to Example 11 of D3 (WO '624). Figure 3 shows lansoprazole pellets according to Example 1 of the present application. As can be observed from Figures 1 and 2, those pellets produced according to Example 11 of WO '624 rapidly underwent a color change signifying the degradation, or lack of stability, of the

active ingredient in the respective formulations. Such rapid degradation was to be expected. See EP 0247983 and EP 244380 which are believed to contain the same disclosure as U.S. Patent Nos. 4,853,230 and 4,786,505 (the Lovgren patents) respectively. As can be seen from Figure 3 of Annex 1, pellets produced according to the present invention, remained stable. See Paragraph 15 of the enclosed declaration.

Following the procedure of Example 11 of WO '624 to produce pellets without an intermediate separating layer between the active containing region and enteric coating will not produce a stable product. Thus, one cannot alter a prior art formulation or process for making a formulation merely by not performing the step of adding a separating layer and still obtain a stable formulation.

Correction of the Interview Summary of May 18, 2006 telephone interview and entry of the enclosed Molina-Millián declaration are earnestly solicited.

It is believed that no fees or charges are required at this time in connection with the present application. However, if any fees or charges are required at this time, they may be charged to our Patent and Trademark Office Deposit Account No. 03-2412.

Respectfully submitted,
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Enclosure: Molina-Millián Declaration w/Annex